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UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF CALIFORNIA
SAN FRANCISCO DIVISION

ABBOTT DIABETES CARE INC. and
 ABBOTT LABORATORIES

Plaintiffs/Counterdefendants,

v.

ROCHE DIAGNOSTICS CORPORATION,
 ROCHE DIAGNOSTICS OPERATIONS,
 INC. and BAYER HEALTHCARE LLC,

Defendants/Counterplaintiffs.

CASE NO. 05-CV 3117 MJJ (BZ)

**DEFENDANTS BAYER AND ROCHE'S
 JOINT MOTION FOR SUMMARY
 JUDGMENT OF INVALIDITY OF THE
 '745 PATENT**

Date: December 12, 2007
 Time: 10:00 a.m.
 Place: Courtroom 11, 19th Floor
 Judge: Hon. Martin J. Jenkins

PUBLIC VERSION

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I. INTRODUCTION

Defendants Bayer Healthcare LLC (“Bayer”), Roche Diagnostics Corp. and Roche Diagnostics Operations, Inc. (“Roche”) (collectively “defendants”) move for summary judgment of invalidity of U.S. Patent No. 6,592,745 (the “‘745 Patent”) on the following grounds:

1) Claim 28 of the ‘745 Patent, the only claim asserted against Bayer, is anticipated by U.S. Patent No. 6,071,391 (the “Gotoh Patent”), as well as by strips developed by Cambridge Sensors Ltd. (“CSL”) and used at Bayer’s facilities in Indiana in April 1998;

2) All of the asserted claims (except for claim 11) are anticipated by WO98/35225 (the “‘225 reference”);

3) Claim 11 is obvious in light of the ‘225 reference in combination with any one of a number of other references in the prior art;

4) All of the asserted claims are invalid under 35 U.S.C. § 112 because the full scope of the claims is not enabled, and the term “measurement zone” is indefinite.

II. BACKGROUND

The ‘745 Patent involves disposable test strips that are used with meters to determine blood glucose concentration. The sample chamber of these test strips includes at least two electrodes, commonly called a working electrode and a counter electrode. (Ex. 1 (‘745 Patent) at 7:61-67.)¹ The sample chamber also contains at least two different chemicals, namely, a mediator and an enzyme (collectively known as “reagents”). (*Id.* at Abstract [57].) When blood enters the sample chamber, the enzyme catalyzes a chemical reaction during which the glucose molecules give up electrons that are picked up by the mediator. This “redox” reaction causes the blood glucose molecules to lose electrons (“oxidize”) and the mediator molecules to gain electrons (“reduce”). When the meter applies a potential, the reduced mediator molecules that diffuse to the working electrode transfer their electrons to (are “electro-oxidized” by) the working electrode. The meter determines the glucose concentration by measuring this electro-oxidation.

¹ All references to exhibits are attached to the Declaration of Parisa Jorjani in Support of Defendants Bayer and Roche’s Joint Motion for Summary Judgment of Invalidity of the ‘745 Patent.

1 The '745 Patent discloses three ways to determine the concentration of glucose in whole
2 blood: coulometry, potentiometry, and amperometry. (Ex. 1 ('745 Patent) at Abstract [57], 6:12-13,
3 6:20-29, 7:19-21.) In a coulometric test, the glucose concentration is determined by totaling up the
4 *charge* derived from all of the glucose in a defined volume. (*Id.* at 6:20-29.) In an amperometric
5 test, the glucose concentration is determined by measuring the *current*, *i.e.* the rate of flow of the
6 electrons, from the volume above the working electrode, with the magnitude of the current being
7 proportional to the concentration of glucose. (Ex. 2 (Bard Dep. 10/18/2007) at 291:9-292:11.) Claim
8 28 of the '745 Patent is limited to amperometric testing. (Ex. 1 ('745 Patent) at 65:1-2.)

9 The '745 Patent also discloses at least two different ways of configuring the electrodes. The
10 electrodes can be placed on the same substrate such that they are in a "co-planar" configuration. (Ex.
11 1 ('745 Patent) at 3:31-33, 3:51-54, Fig. 2.) The electrodes can also be on separate substrates in a
12 facing configuration. (*Id.* at 3:18-24, 3:46-50, Fig. 1.) The claims are not limited to a specific
13 electrode configuration.

14 The reaction in glucose test strips can also produce a current from sources other than glucose,
15 which may adversely affect the accuracy of the measurement. This current is generally called a
16 background signal. (Ex. 3 (Claim Construction Order, filed 4/27/2007) at 25.) The '745 Patent is
17 focused on limiting a certain type of background signal, specifically that resulting from mediator
18 shuttling. Shuttling occurs when a mediator that has given up its electron at the working electrode
19 diffuses to the counter electrode, picks up an electron there that does not come from glucose, then
20 travels back to the working electrode and gives it up there. (*Id.* at 27.) As defined by the '745 Patent
21 and interpreted by the Court shuttling is the only background signal in the claims. (*Id.* at 25.)

22 **III. LEGAL STANDARD**

23 Summary judgment is appropriate when there is no genuine issue of material fact and the
24 moving party is entitled to judgment as a matter of law. *See* Fed. R. Civ. P. 56(c). In the case of an
25 anticipation defense, courts should grant summary judgment where, as here, the undisputed facts
26 show that the prior art meets the limitations of the claim at issue. *See Telemac Cellular Corp. v.*
27 *Topp Telecom, Inc.*, 247 F.3d 1316, 1327 (Fed. Cir. 2001). To meet the limitations of the disputed
28

claim, the anticipating prior art need not use the same language as the patent-in-suit; rather, it is simply necessary that the elements of the claim be part of a single prior art reference. *See Helifix, Ltd. v. Blok-Lok, Ltd.*, 208 F.3d 1339, 1346-47 (Fed. Cir. 2000).

Summary judgment on the invalidity of a patent claim is also warranted when the claim is not supported by an enabling disclosure. *See e.g., Nat'l Recovery Techs., Inc. v. Magnetic Separation Sys., Inc.*, 166 F.3d 1190, 1198 (Fed. Cir. 1997) (affirming summary judgment of invalidity for lack of enablement). A court considering a motion for summary judgment must consider the burden on the patent specification to teach "those skilled in the art how to make and use the full scope of the claimed invention without 'undue experimentation.'" *Genentech, Inc. v. Novo Nordisk A/S*, 108 F.3d 1361, 1365 (Fed. Cir. 1997) (quoting *In re Wright*, 99 F.2d 1557, 1561 (Fed. Cir. 1993)).

IV. ANALYSIS

A. The Gotoh Patent Invalidates Claim 28 of the '745 Patent

The Gotoh '391 Patent was filed on December 15, 1997, before Plaintiff's earliest alleged conception date, and is prior art under 35 U.S.C. § 102(e). (Ex. 4 (Gotoh Patent) at [22]; Ex. 5 (Abbott's Supp. Resp. 9/12/2007) at 3 (alleging conception date of July 30, 1998)). Gotoh discloses at least two examples of test strips that meet every limitation of claim 28 of the '745 Patent. Example B1 of Gotoh describes a blood glucose test strip with working and counter electrodes separated by 140 μm (microns), and enzyme and mediator placed on the working electrode. A 1 μL (microliter) sample was added to the strip, and, after a 20-second rest period, a potential was applied for 10 seconds. The current was then measured, and the strip achieved an accuracy level in line with commercial strips. (Ex. 6 (Bard Dep. 10/19/2007) at 395:15 - 398:10.) Gotoh Example D1 describes a similar strip with electrodes spaced 230 μm apart. As explained below, these strips practice the method of claim 28. Representative figures are attached as Appendix A.

As stated in **the preamble of claim 28**, the Gotoh Patent discloses a "method for determining a concentration of glucose in a sample." (*See* Ex. 4 (Gotoh Patent) at 1:44-58.)

As required by **claim 28 (a)**, the Gotoh Patent discloses "contacting a sample with an electrochemical sensor." (*See* Ex. 4 (Gotoh Patent) at 8:24-39, 12:34-50.)

As required by **claim 28 (a)(i)**, the Gotoh patent discloses working and counter electrodes “separated by a closest distance no greater than 1000 μm .” In examples B1 and D1, both of which have electrodes in a facing configuration, the distance between the electrodes is 140 μm and 230 μm , respectively.² (Ex. 4 (Gotoh Patent) at 7:56-8:10, 12:4-33.)

Claim 28 (a)(ii) requires a “measurement zone ... sized to contain a volume of no more than about 1 μL of the sample.” The ‘745 Patent defines “measurement zone” as “a region of the sample chamber sized to contain only that portion of the sample that is to be interrogated during an analyte assay.” (Ex. 1 (‘745 Patent) at 7:7-9.) Abbott stipulated to this definition in the claim construction process.³ Examples B1 and D1 each disclose methods using a *total* sample volume of 1 μL . (Ex. 4 (Gotoh Patent) at 8:24-26, 12:34-36.) The maximum amount of sample “interrogated” cannot be larger than the 1 μL of volume present in the Gotoh strips. Because the measurement zone is sized to contain a “*portion* of the sample that is to be interrogated,” and the *total* sample volume is 1 μL , the measurement zone in Examples B1 and D1 must be within the 1 μL claim limitation. (See Ex. 3 (Claim Construction Order) at 22 (emphasis added)).

Abbott itself stated in its Final Infringement Contentions that “[t]he measurement zone cannot be larger than the total amount of blood in the strip.”⁴ (Ex. 10 (Final Infringement Contentions – Bayer 5/29/2007) at Ex. 2, p. 3.)

² The 140 μm electrode spacing in Example B1 is calculated by subtracting 20 μm (thickness of two 10 μm carbon electrodes) from 160 μm (thickness of the adhesive tape). The electrode spacing in Example D1 is calculated in the same way except that the thickness of the spacer is 250 μm (0.25 mm), resulting in 230 μm .

³ Ex. 9 (Claim Construction Statement, filed 10/24/2006), Exh. 2 at 1.

⁴ Claims are construed the same way for both invalidity and infringement. *Eaton Corp. v. Rockwell Int’l Corp.*, 323 F.3d 1332, 1343 (Fed. Cir. 2003).

1 [REDACTED] This does not conform to a plain reading
2 of the '745 Patent, which defines measurement zone as a "portion" of the sample. This is also
3 contrary to Abbott's position that the measurement zone can be no larger than the total sample in the
4 test strip. Thus, the amount of sample "interrogated during the analyte assay" cannot be larger than
5 the 1 μ L of volume actually present in Examples B1 and D1.

6 [REDACTED]
7 [REDACTED]
8 [REDACTED]
9 [REDACTED]
10 [REDACTED] The Gotoh patent cannot be so interpreted, for many reasons.

11 First, the quoted passage does not disclose a single sensor that can accommodate a range of
12 sample sizes of 0.5 to 10 μ L. It provides a range of different sensors that can be made. The same
13 paragraph discloses a range of voltages (0.4 to 1.2 V) and test times (1 to 120 seconds) as well. (Ex.
14 4 (Gotoh Patent) at 5:40-42.) This does not mean that a single "thus-manufactured strip" can operate
15 at the full range of these samples sizes, voltages, and test times. The Gotoh Patent discloses many
16 different embodiments, but never states that the sensor is configured to utilize a wide range of sample
17 sizes.

18 [REDACTED]
19 [REDACTED] In particular, it does not apply to Examples B1 and D1
20 and their related figures. The Gotoh Patent is divided into sections based on the various figures
21 [REDACTED]

22 at 3:37-6:62.) Example B1, however, is in the section pertaining to Figures 6 through 9. (*Id.* at 6:63-
23 9:5.) Example D1 relates to Figures 11-14. (*Id.* at 9:63-13:34.) Thus, Gotoh does not suggest that
24 the devices disclosed in Examples B1 and D1 may have a measurement zone of more than 1 μ L.

25 **Claim 28 (a)(ii)** also requires the measurement zone to be "adjacent to the working electrode
26 and the counter electrode." In its Claim Construction Order, this Court defined the term "adjacent" to
27 mean that the "measurement zone is next to (whether or not touching) both the working electrode and
28

the counter electrodes, with no structure intervening between either electrode and the measurement zone.” (Ex. 3 (Claim Construction Order) at 24.) Examples B1 and D1 disclose embodiments having facing electrodes spaced 140 and 230 μm apart, formed by placing a working electrode on one base, a counter electrode on a second base, then spacing the two bases apart using a spacer or double-sided tape. (See Ex. 4 (Gotoh Patent) at 7:24-40, 8:1-6, 12:26-33.) There is no disclosure of any “intervening structure” between these electrodes.

Abbott has not disputed that the Gotoh patent discloses this element. (Ex. 7 (Bard Rebuttal) at 22.)

Claim 28 (a)(iii) requires that an enzyme and diffusible mediator is disposed within the measurement zone. Examples B1 and D1 use an analyte-responsive enzyme (glucose oxidase) and a diffusible mediator (ferricyanide) coated above the working electrode (and therefore in the measurement zone). (See Ex. 4 (Gotoh Patent) at 7:58-67, 12:14-21.)

Pursuant to **claim 28(b)**, the test strips disclosed by the Gotoh patent hold the sample within the measurement zone in a non-flowing manner. In the related BD case, the Court construed the term “non-flowing” in a sister patent to mean that the sample is “not moving” during measurement. (Ex. 11 (Claim Construction Order (BD)), dated 8/31/2006) at 15-16.)⁶ In Example B1, the sample is “allowed to stand for 20 seconds” before the voltage is applied. (See Ex. 4 (Gotoh Patent) at 8:24-28.) In Example D1, it is allowed to stand for 80 seconds. (*Id.* at 12:38.) Gotoh also discloses that the sample is “precisely caught” in the strip, teaching that it is not allowed to continue moving at the time of measurement. (See, *id.* 5:62-63.) Accordingly, the sample is “at rest” during the measurement.⁷ (Ex. 6 (Bard Dep.) at 411:25 - 412:19, 413:24 - 414:13.)

⁵ See Ex. 12 (Abbott’s Amended Resp. 7/20/2007) at 3-4; Ex. 10 (Final Infringement Contentions – Bayer) at Ex. 2, p. 3; Ex. 13 (Dep. of E. Heller 8/17/2007) at 572:20 - 573:11; Ex. 14 (30(b)(6) Dep. of Feldman 6/20/2007) at 33:6 - 34:5, 42:17 - 43:8.

⁶ Bayer and Roche respectfully request the Court to take judicial notice of this record from the Court’s files.

⁷ Turner Decl. at ¶ 27; *accord* Ex. 14 (30(b)(6) Dep. of Feldman) at 329:24 - 331:9; Ex. 15 (Dep. of Feldman 8/14/2007) at 280:22 - 281:16; Ex. 13 (Dep. of E. Heller 8/17/2007) at 524:25 - 525:7.

1 Examples B1 and D1 also meet the requirement of **claim 28(c)** requiring that the background
 2 signal generated by shuttling be less than five times the signal generated by an average normal
 3 physiological amount of glucose (the analyte). This Court has previously construed the phrase
 4 “background signal that is generated by the redox mediator” as “background signal that is created by
 5 the shuttling of the redox mediator back and forth between the working and counter electrodes during
 6 the measurement period.” (Ex. 3 (Claim Construction Order) at 26.) Thus, shuttling requires the
 7 mediator molecule to travel from the working electrode to the counter electrode and back again. (*Id.*)

8 Based on the formula taught by the ‘745 Patent and the prior art, the electrodes in Examples
 9 B1 and D1 of Gotoh are too far apart, and the measurement period is too short, for shuttling to occur.
 10 Specifically, according to the ‘745 Patent, no shuttling will occur when the electrodes are spaced far
 11 enough apart:

12 [i]n some amperometric . . . embodiments, the redox mediator
 13 circulation is decreased by separating the working electrode from the
 14 counter or counter/reference electrode such that the distance through
 15 which the redox mediator would diffuse during the measurement period
 16 is no greater than, for example, the distance between the electrodes. A
 redox mediator can diffuse a distance equal to $(D_m t)^{1/2}$, where D_m is the
 effective diffusion coefficient for the medium between the electrodes
 and t is time.⁸

17 (Ex. 1 (‘745 Patent) at 43:49-57.) According to this teaching, one can use the $(D_m t)^{1/2}$ formula to
 18 determine how far the mediator will travel and choose a suitable electrode spacing to avoid shuttling.
 19 (*Id.*; see also 49:38-41 (“[i]n some instances, the distance between electrode pairs is sufficient that
 20 redox mediator and/or enzyme do not substantially diffuse between electrode pairs during the
 21 measurement period ...”).) The ‘745 Patent provides an example of how to space the electrodes to
 22 diminish shuttling, given a diffusion coefficient between 10^{-5} and 10^{-6} cm²/s and a test time of 30
 23 seconds. (*Id.* at 43:57-62.) The patent teaches that the electrodes should be at least 100 microns

1 apart. (*Id.*) This same formula can be used to determine whether shuttling occurs in the examples of
 2 the Gotoh Patent.⁹

3 In Gotoh Examples B1 and D1, the distance between the electrodes is 140 μm and 230 μm ,
 4 respectively. (Ex. 4 (Gotoh Patent) at 7:56-8:10, 12:26-33.) Thus, to shuttle from the working
 5 electrode to the counter electrode *and back* as required by the claims, the mediator would need to
 6 travel 280 μm in Example B1 and 460 μm in Example D1. [REDACTED]

7 [REDACTED] In both examples, the test time when potential is applied and shuttling may occur is
 8 10 seconds. (Ex. 4 (Gotoh Patent) at 8:24-29, 12:34-39.) The mediator disclosed in Gotoh is
 9 ferricyanide, which Abbott has stated has a diffusion coefficient of $7.6 \times 10^{-6} \text{ cm}^2/\text{s}$ in buffer. (Ex. 6
 10 (Bard Dep.) at 376:25 - 377:6.) Applying the $(D_{\text{mt}})^{1/2}$ formula, the mediator in the Gotoh strips would
 11 diffuse a distance of approximately 87 μm during the 10-second measurement period in buffer. Thus,
 12 according to the teaching of the '745 Patent, the mediator would not travel far enough during the
 13 measurement period to cause any shuttling. (Turner Decl. ¶29.) The lack of shuttling is confirmed
 14 by the fact that when the electrodes in Gotoh Example D1 were moved from 230 to 140 μm apart,
 15 there was no increase in current signal: the average measurement was 24.0 μA at 230 μm and 23.7
 16 μA at 140 μm .¹⁰ (Ex. 4 (Gotoh Patent) at 12:49, 13:24.)

17 [REDACTED]
 18 [REDACTED] However, Plaintiff's expert
 19 theories cannot change the teachings of the patent, which specifically uses $(D_{\text{mt}})^{1/2}$ to determine the
 20 electrode spacing required to avoid shuttling. (Ex. 1 ('745 Patent) at 43:49-57.) [REDACTED]

21 [REDACTED]
 22 [REDACTED]
 23 [REDACTED]
 24 [REDACTED]
 25 ⁹ [REDACTED]
 26 [REDACTED]
 27 ¹⁰ The 140 μm electrode distance is calculated by subtracting 20 μm (thickness of two 10 μm
 28 carbon electrodes from 160 μm (thickness of the adhesive tape used in Example D3).

1 In any event, even using Dr. Bard's modified formula ($2(D_{mt})^{1/2}$) for calculating background
2 signal, Gotoh examples B1 and D1 meet element 28(c). [REDACTED]

3 [REDACTED]
4 [REDACTED]
5 [REDACTED]
6 [REDACTED] As discussed
7 above, to shuttle from the working electrode to the counter electrode and back, the mediator would
8 need to travel 280 μm in Example B1 and 460 μm in Example D1 of Gotoh. Thus, even using Dr.
9 Bard's modified formula, the mediator cannot make the required round trip back to the working
10 electrode to contribute to the background signal due to shuttling.

11 Finally, as required by **claim 28 (d)**, Examples B1 and D1 disclose determining the
12 concentration of the glucose using current, *i.e.*, by amperometry. (*See* Ex. 4 (Gotoh Patent) 8:28,
13 12:38.)

14 Accordingly, the Gotoh reference meets all elements of Claim 28.

15 **B. The CSL Strip Invalidates Claim 28 of the '745 Patent.**

16 Claim 28 of the '745 Patent is also rendered invalid by the CSL test strips under 35 U.S.C.
17 §102 (g). CSL is a UK company headed by James McCann that develops and manufactures blood
18 glucose test strips, including a strip currently sold in the United States. (Ex. 16 (CSL website, dated
19 7/13/2007) at BAYER0402567 to -68 & -71 to -72.) In April 1998, a CSL employee, Neil Blair,
20 brought a batch of its glucose test strips (bearing lot number 7J2210) to Bayer's laboratories in
21 Indiana. (Ex. 17 (McCann Dep. 7/19/2007) at 46:25-47:24.) On April 28 and 29, 1998, these strips
22 were used at Bayer to measure the glucose concentration in whole blood of 36 diabetic patients. (Ex.
23 17 (McCann Dep.) at 47:23-48:23; Ex. 18 (Blair Dep.) at 12:20-19:1; Ex. 19 (McCann Def. Dep. Ex.

24
25 11 [REDACTED]
26 However, Gotoh states that the measurement is made "10 seconds from the application" of the
27 voltage. (Ex. 4 (Gotoh Patent) at 8:24-29, 12:34-39.) Thus, the relevant time is 10 seconds, not 20.
28 (Ex. 6 (Bard Dep.) at 396:18-397:18; Ex. 2 (Bard Dep.) at 61:10 - 62:6.) [REDACTED]

247).) Accordingly, the method of the CSL strips was practiced in the United States before Abbott's invention date and was reduced to practice before that date.¹²

1. The CSL Strip Meets Every Limitation of Claims 28 of the '745 Patent.

When used in April 1998, the CSL strips met all of the elements of Claim 28, as follows:

Claim 28 preamble. The CSL strips were used in a "method for determining a concentration of glucose." (Ex. 17 (McCann Dep.) at 47:23-48:23; Ex. 19 (McCann Def. Dep. Ex. 247).)

Claim 28(a). The CSL strips contacted blood samples. (*Id.*)

Claim 28 (a)(i). The distance between the working and counter electrodes on the CSL strips is less than 1000 μm . Specifically, the working electrode in the CSL strip is comprised of a carbon conducting layer with mediator and a reagent layer deposited on top. (Turner Decl. ¶¶ 39-40.) The CSL strip also includes a counter electrode comprised of a carbon conducting layer with a square of silver-silver chloride ("Ag/AgCl") deposited on top. (*Id.*) The carbon conducting layers of the two electrodes are separated by a closest distance of approximately 500 μm . (Ex. 17 (McCann Dep.) at 60:15-64:7.) This is consistent with measurements made on an actual CSL strip from the lot brought to Bayer in April 1998, in which the electrode distance was determined to be approximately 538 μm . (Turner Decl. ¶¶ 45-46; Stetter Decl. ¶¶ 32-34; (Ex. 17 (McCann Dep.) 46:25-47:22, 58:10-59:16.)

Claim 28 (a)(ii). The CSL strips had a total sample chamber volume of no more than about 1 μL . (Ex. 17 (McCann Dep.) at 78:8-83:15; Turner Decl. ¶¶ 37; 55.) Because the measurement zone in the '745 Patent is by definition a "region" of the sample chamber and a portion of the sample, *see* Ex. 1 ('745 Patent) at 7:7-9, the measurement zone of the CSL test strip also must have a volume of less than 1 μL .¹³ The CSL strip also does not have any structure intervening between the working

¹² Abbott has recently asserted an earliest conception date of July 30, 1998. (Ex. 5 (Abbott's Supp. Resp.) at 3.) The CSL strips were reduced to practice before that date when they were used in the United States in April 1998. *Shurie v. Richmond*, 699 F.2d 1156, 1158 (Fed. Cir. 1983) (a process is not reduced to practice in the United States unless it is performed in this country); *Scott v. Koyama*, 281 F.3d 1243, 1247 (Fed. Cir. 2002) (same); *Boston Sci. Corp v. Johnson & Johnson*, 481 F. Supp. 2d 1018, 1028 (N.D. Cal. 2007) ("processes must be performed in the United States to be actually reduced to practice.").

¹³ Abbott stipulated to this definition in the claim construction process. (Ex. 9 (Claim Construction Statement) at Exh. 2 at 1).

1 and the counter electrodes. (Ex. 20 (Def. Dep. Exs. 249 & 250); Turner Decl. ¶ 36.) Abbott has not
2 disputed that the CSL strip meets these limitations. (Ex. 7 (Bard Rebuttal) at 25.)

3 **Claim 28 (a)(iii).** The CSL strip has an “analyte-responsive enzyme” (glucose
4 dehydrogenase) and a “diffusible redox mediator” (medola blue) on the working electrode and
5 therefore in the measurement zone. (Ex. 17 (McCann Dep.) at 22:15-23:6; 26:14-21.)

6 **Claim 28 (b).** The CSL strip was used in a “non-flowing manner.” (Ex. 18 (Blair Dep.) at
7 36:18-24.)

8 **Claim 28 (c).** Tests performed by CSL demonstrate that the CSL test strips met the
9 background signal limitation of claim 28 of the ‘745 Patent.¹⁴ Because the *total* background signal
10 for those strips is less than five times the signal generated at approximately a normal physiological
11 amount of glucose, the CSL test strip meets the ratio required by claim 28 of the ‘745 Patent. (*Id.*)
12 Abbott has not disputed that the CSL strip meets this limitation of claim 28. (Ex. 7 (Bard Rebuttal) at
13 25; Ex. 6 (Bard Dep.) at 394:9-11.)

14 **Claim 28 (d).** The CSL strips used amperometry. (Ex. 22 (BAYER0397609-10; 0266791-
15 96).)

16 **2. Abbott’s Argument Is Based on Faulty Measurements and Should Be
17 Disregarded.**

18 [REDACTED] element (a)(i),
19 that the closest distance between the working and counter electrodes in the CSL strips must be no
20 more than 1000 μm . [REDACTED]

21 [REDACTED] Abbott’s argument fails to raise a genuine
22 issue of fact because Abbott measured the wrong dimension of the CSL strip.

23 The relevant distance under claim 28(a)(i) is the distance between the working electrode and
24 the counter electrode. [REDACTED]

25
26 ¹⁴ See Ex. 18 (Blair Dep.) 19:2-21:15; 24:13-35:1 & (Ex. 21 (Def. Ex. 285) (showing total
27 background signal of 0 in buffer and 0.4 nA in whole blood, and normal signal of 1.12 nA); Turner
28 Decl. ¶ 60 & Table 3.

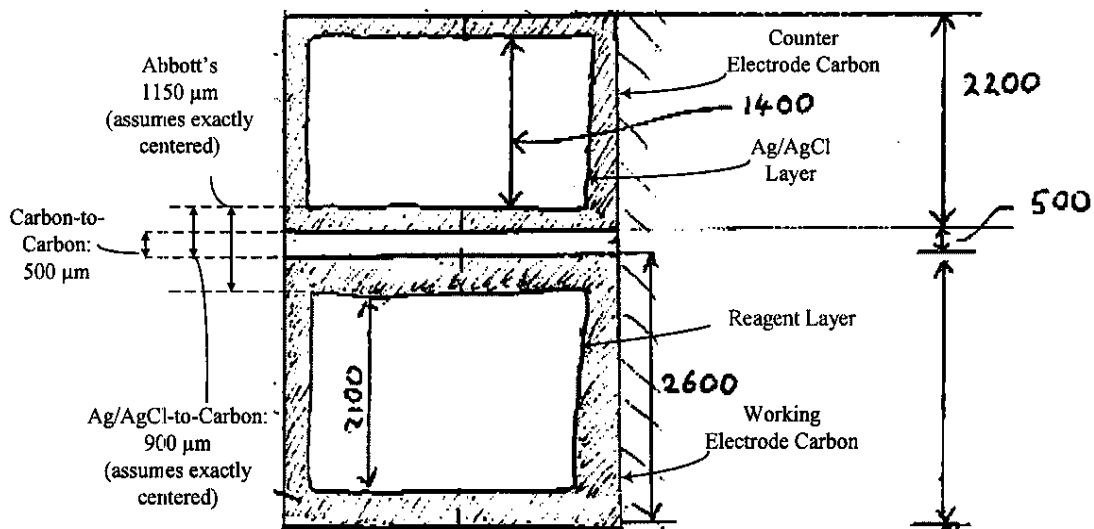


Figure 1

As shown in Figure 1 above, the working and counter electrodes include *both* a carbon layer and a reagent and Ag/AgCl layer, respectively.

Moreover, the patent discloses that the conducting layer (*e.g.* carbon) is part of the working electrode. (Ex. 1 ('745 Patent) at 8:8-15, *see also* at 59:1-8 (describing placing reagent on only "a portion of" the working electrode).)

Thus, using the correct definition of working electrode and Abbott's measurement, the distance is still less than 1000 μm.

Abbott's argument is also unsupported by actual evidence,

But it is plain from an actual photograph of a CSL strip that the reagent layers are *not* centered on the carbon. (Turner Decl.

Ex. C.) As explained in the Turner Declaration, measurements of the actual CSL strip show that the distance between the electrodes is less than 1000 μm regardless of whether one measures the distance between the carbon layers, the distance between the Ag/AgCl of the counter and the carbon of the working electrode, or even, as Abbott proposes, the distance between the Ag/AgCl and the reagent layer on top of the working electrode. (Turner Decl. ¶ 47).

3. CSL Did Not Abandon, Suppress, or Conceal the Method of Using the Strips Under 35 U.S.C. Section 102(g).

Once defendants show with clear and convincing evidence that CSL was the first to reduce the methods to practice in the United States, the burden shifts to Abbott to produce evidence sufficient to create a genuine issue of material fact as to whether CSL abandoned, suppressed, or concealed the invention. *Apotex USA Inc. v. Merck & Co. Inc.*, 254 F.3d 1031, 1037-38 (Fed. Cir. 2001).

In connection with the development of its glucose strips, CSL filed several patent applications, and was granted at least one United States Patent.¹⁵ Moreover, CSL consistently engaged in negotiations with various business partners in an effort to manufacture and sell its novel glucose strip.

In 2001, CSL developed a business partnership with CHDiagnostics, the company which ultimately brought the CSL strip to market in 2003 (sold under the SeNova brand).¹⁶ The SeNova strip meets the limitations of claim 28 of the '745 Patent. (Turner Decl. ¶¶ 64-66.) Thus, the CSL strip was not abandoned, suppressed or concealed. *Apotex*, 254 F.3d at 1037-38; *Checkpoint Sys., Inc. v. U.S. Int'l Trade Comm'n*, 54 F.3d 756, 761 (Fed. Cir. 1995).

¹⁵ See, e.g., Ex. 26 (WO98/55856); Ex. 27 (WO0028068); Ex. 28 (U.S. Pat. No. 6,436,256); Ex. 29 (US2006/0287035).

¹⁶ Ex. 17 (McCann Dep.) at 103:1-105:25; 108:2-109:8; Ex. 16 (CSL website); Ex. 30 BAYER0402570 (FDA 510(k) for SeNova).

C. The Heller '225 Reference Anticipates All But One Asserted Claim of the '745 Patent.

Roche submitted the expert report of Stephen G. Weber, Ph.D., in support of its position that the '745 patent is invalid because it was anticipated and obvious. In his report, Dr. Weber concluded that all of the asserted claims of the '745 Patent, except claim 11 (which is obvious as shown below), are anticipated under 35 U.S.C. § 102(a) by at least WO98/35225, a published patent application ("Heller '225 reference"). (Weber Dec. at Ex. 1: 42-46.)¹⁷ The Heller '225 reference was published on August 13, 1998, before the earliest filing date of the '745 Patent. (*Id.*)

In the text of his report and an accompanying claim chart, Dr. Weber analyzed every element of the asserted claims and, except for claim 11, found them all present in the Heller '225 reference.¹⁸ (Weber Dec. Ex. 1 at 42-46 and '225 claim chart.)

For the reasons given below, Dr. Bard's response concedes the invalidity of the '745 Patent.

¹⁷ This motion is supported by a Declaration of Dr. Weber that verifies his invalidity report.

¹⁸ Dr. Weber concluded that claim 8 of the '745 patent is disclosed by the Heller '225 reference but that the disclosure is not enabling. In the next section of this brief, Defendants demonstrate that the '745 patent is invalid because the specification does not enable the full scope of the claims. If the Court disagrees with that argument, then claim 8 of the '745 patent is likewise anticipated by the Heller '225 reference.

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12 Although Dr. Weber's analysis coupled with Dr. Bard's failure to dispute it should end the
13 matter, the Heller '225 reference in fact expressly discloses a diffusible mediator:

14 More preferably, the redox mediators of the present invention are
15 bound or otherwise immobilized on the working electrode 22 to prevent
16 undesirable leaching of the mediator into the sample. *A diffusing or
leachable (i.e., releasable) redox mediator* is not desirable when the
working and counter electrodes are close together. . . .

17 (Ex. 23 ('225 reference) at 9:25-29 (emphasis added).)¹⁹ A reference anticipates an invention even if,
18 after disclosing the invention, the reference then disparages it. *Upsher-Smith Labs., Inc. v. PamLab,*
19 *L.L.C.*, 412 F.3d 1319, 1323 (Fed. Cir. 2005); *Celeritas Techs., Ltd. v. Rockwell Int'l Corp.*, 150 F.3d
20 1354, 1361 (Fed. Cir. 1998)). Thus, "the question whether a reference 'teaches away' from the
21 invention is inapplicable to an anticipation analysis." *Id.* Given the Heller '225 reference's express
22 disclosure of a diffusible mediator, Dr. Bard's report cannot create a genuine issue of material fact to
23

24 ¹⁹ The '225 reference also discloses that "almost any organic or organometallic redox species
25 can be used as a redox mediator," such as, for example, Nile blue, indophenol, quinones and
26 quinhydrones, including ferricyanide. (Ex. 23 ('225 reference) at 10:13-25, 11:14). In the '225
27 reference, independent claim 127 calls for a "redox mediator on its working electrode" and its
28 dependent claim 128 states that the redox mediator is a non-leachable mediator, implying that redox
mediator in claim 127 necessarily includes a leachable mediator. (*Id.* at 63). The claims of a patent
are part of its specification and disclosure. 35 U.S.C. § 112; *In re Dossel*, 115 F.3d 942, 945 (Fed.
Cir. 1997).

1 preclude summary judgment. [REDACTED]
2 [REDACTED]

3 Additionally, Abbott is judicially estopped from denying that the Heller '225 reference
4 discloses a diffusible mediator. During the Markman proceedings in the related cases against Becton
5 Dickinson and Nova Biomedical, Abbott argued that claim 16 of the '164 Patent could not be limited
6 to an immobilized mediator because an immobilized mediator was simply a preferred embodiment,
7 *i.e.*, other embodiments had diffusible mediators. *See* Docket No. 189-1 in Case No. 3:04-cv-02123-
8 MJJ at 16-17 ("The specification makes clear that immobilized mediators are aspects of preferred
9 embodiments. . . . It is likewise irrelevant that the patent expresses a strong preference for
10 immobilized mediators. . . . [I]dentification of an option as inferior is not enough to exclude it from
11 the scope of the claim.").²⁰ To have "identified" an option of using immobilized mediators, the '164
12 Patent must have disclosed diffusible mediators. Similarly, in the slides for the Markman hearing on
13 the '164 Patent, to support its position that "[i]mmobilized mediators are merely preferred" in the
14 '164 Patent/Heller '225 reference, among other passages from the '164 Patent Abbott cited Column 6
15 at lines 26-30, the same passage from the Heller '225 reference quoted above that expressly discloses
16 a diffusible mediator. (Ex. 24 (Abbott's 164 Markman slides) at Slide 64.) Abbott prevailed on its
17 argument that immobilized mediators were simply a preferred embodiment, such that claim 16 of the
18 '164 patent covered other mediators as well, including diffusible mediators. (Ex. 11 (Claim
19 Construction Order) at 14.)²¹ When agreeing with Abbott's argument, the Court also relied on the
20 language from the '164 Patent/Heller '225 reference that expressly discloses a diffusible mediator
21 and is set out above. (*Id.*)

22 Having successfully urged the position that the '164 Patent/Heller '225 reference discloses
23 and covers diffusible mediators, Abbott is judicially estopped from contending otherwise now.
24 "Judicial estoppel" applies when a party takes a later position that is inconsistent with a former

25 ²⁰ Bayer and Roche respectfully request the Court to take judicial notice of this record from
26 the Court's files.

27 ²¹ Bayer and Roche respectfully request the Court to take judicial notice of this record from
28 the Court's files.

position in the same dispute, on which the party had been successful and had prevailed based on the former position.” *Bonzel v. Pfizer, Inc.*, 439 F.3d 1358, 1362 (Fed. Cir. 2006); *see also Transclean Corp. v. Jiffy Lube Int’l, Inc.*, 474 F.3d 1298, 1307 (Fed. Cir. 2007) (“the underlying purpose of the doctrine is to protect the integrity of the judicial process.”); *U.S. v. Lence*, 466 F.3d 721, 726 (9th Cir. 2006). Because Abbott prevailed on its earlier position, it is judicially estopped from asserting a contrary position.

D. The Asserted Claims are Obvious as a Matter of Law.

To the extent that any element is found to be missing from the Gotoh Patent, the CSL strip, or the Heller reference, it would have been obvious to a person of ordinary skill in 1998 to combine the references. *KSR Int’l Co. v. Teleflex Inc.*, 127 S. Ct. 1727 (U.S. 2007).²² All of these references relate to the same field, specifically glucose sensors, and a person of skill in the art in 1998 would have been motivated to combine them to practice the methods of the ‘745 Patent. A person of skill in the art would have been motivated to measure glucose concentration using a sensor having a very low background such as the CSL strip, having a small volume such as the CSL and Gotoh strips, and having electrodes separated by a small distance, such as the Gotoh strip.

In particular, claim 11 of the ‘745 patent adds to claim 1 the further limitation that the glucose concentration is determined “by a measurement technique from the group consisting of chronoamperometry and Cottrell-type measurement techniques using the sensor signal.” (Ex.1 (‘745 Patent) at 62:59-62.) In his report, Dr. Weber stated that each of the other four references he applied against claim 11 taught this element. (Weber Dec. at Ex. 1, 56-58.) In the claim chart for the Heller ‘225 reference attached to his report, Dr. Weber stated that chronoamperometry and Cottrell-type

²² In *KSR*, the Supreme Court rejected the Federal Circuit’s more stringent “teaching, suggestion, or motivation” test for obviousness in favor of a more flexible, common sense approach that allows courts greater leeway to grant summary judgment. Indeed, the Court stated that because obviousness is a question of law, “summary judgment is appropriate” where, as here, the scope of the claim, the level of skill in the art, and the content of the prior art are not in material dispute. *Id.* at 1745-46.

1 measurements were well known in the art and cites an additional five U.S. patents. (*Id.* at '225 chart,
 2 at 4.)²³ Any one of these nine references, all from the same field, can be combined with the Heller
 3 '225 reference to produce all the elements of claim 11. The inescapable conclusion is that claim 11 is
 4 obvious as a matter of law.²⁴ *KSR*, 127 S. Ct. at 1727.

5 **E. The '745 Patent is Invalid Because the Term "Measurement Zone" is Indefinite**
 6 **and the Specification Does not Enable the Full Scope of the Claims.**

7 The '745 Patent covers methods of using glucose monitors having a "measurement zone" of 1
 8 microliter or less. (Ex. 1 ('745 Patent) at 61:39-63, 64:45-65:2, 65:37-66:15.) Each claim requires
 9 that this measurement zone: (1) be "positioned adjacent to the working electrode and counter
 10 electrode", (2) be "sized to contain a volume of no more than 1 microliter of the sample;" 3) contain
 11 an "analyte-responsive enzyme and a diffusible redox mediator;" and 4) hold the sample "in a non-
 12 flowing manner[.]" (*Id.* at 61:47-54.) [REDACTED]
 13 [REDACTED]
 14 [REDACTED]

15 [REDACTED] For the reasons
 16 detailed below, the '745 Patent is invalid as a matter of law because the term "measurement zone" is
 17 indefinite, and the patent fails to enable a person of skill in the art to construct or measure a
 18 "measurement zone" in the accused devices. (Weber Dec. Ex. 1 at 23:18-20.)

19 The '745 Patent discusses three different methods to determine blood glucose concentration:
 20 amperometry, coulometry, and potentiometry. (Ex. 1 ('745 Patent) at 6:12-13, 6:20-29, 7:19-21.) All
 21 of the asserted claims cover amperometric methods, and asserted claim 28 in particular is limited to
 22 amperometric methods. Similarly, the '745 Patent discusses two different configurations for the
 23 [REDACTED]
 24 [REDACTED]

25 ²³ [REDACTED]
 26 [REDACTED]
 27 ²⁴ If the Court concludes that the Heller '225 reference does not anticipate claim 8 because the
 28 '225 reference does not enable amperometry, then claim 8 is also obvious as a matter of law based on
 these same references.

1 working and counter electrodes: facing and co-planar. (*See id.* at Figs. 1 and 2.) None of the asserted
2 claim is limited to either electrode arrangement, so all the asserted claims cover both. All of the
3 accused devices have in common that they are amperometric and have co-planar electrodes.

4 The inventors of the '745 Patent were working primarily with coulometric sensors having
5 facing electrodes. Abbott has identified no evidence that any of the named inventors ever conceived
6 and reduced to practice a co-planar, amperometric system covered by the claims of the '745 Patent.²⁵
7 Abbott can cite to no lab notebooks, reports, analyses, memos, emails, or other documents that show
8 that the research that led to the '745 Patent included testing or creation of a co-planar, amperometric
9 device. [REDACTED]
10 [REDACTED]
11 [REDACTED]
12 [REDACTED]
13 [REDACTED]
14 [REDACTED]
15 [REDACTED]

16 [REDACTED] So in order to understand how to construct and
17 determine the volume of the measurement zone, a person of skill in the art must consult the
18 specification of the '745 Patent. [REDACTED]
19 [REDACTED]
20 [REDACTED]

21 [REDACTED] None of the exemplary
22 devices in the '745 Patent are both amperometric and co-planar. (*Id.* at 187:21-189:3.) [REDACTED]
23 [REDACTED]
24 [REDACTED]
25 [REDACTED]
26 [REDACTED]

27 ²⁵ [REDACTED]
28 [REDACTED]

1 [REDACTED]
2 [REDACTED]
3 [REDACTED]
4 [REDACTED]
5 [REDACTED]
6 [REDACTED] *Phillips v. AWH Corp.*,
7 415 F.3d 1303 (Fed. Cir. 2005) (holding that patent claims are of primary importance, and extrinsic
8 evidence is less significant than intrinsic evidence in understanding the patent).

9 Stepping outside the express teaching of the '745 Patent, [REDACTED]
10 [REDACTED]
11 [REDACTED]
12 [REDACTED]
13 [REDACTED]
14 [REDACTED]
15 [REDACTED]
16 [REDACTED]
17 [REDACTED]
18 [REDACTED]

19 The '745 Patent fails to enable a person of skill in the art to construct a co-planar,
20 amperometric sensor that has a measurement zone meeting the requirements of the claims. The
21 Federal Circuit has determined that in such a case, the patent is invalid as a matter of law. *See*
22 *Automotive Techs. Int'l, Inc. v. BMW of N. Am., Inc.*, Case Nos. 2006-1013 & 2006-1037, 2007 U.S.
23 App. LEXIS 21271 (Fed. Cir. Sept. 6, 2007). In *Automotive Techs.*, the patent-in-suit covered a side-
24
25

26 26 [REDACTED]
27 [REDACTED]
28 [REDACTED]

1 impact sensor to deploy an airbag in an automobile accident. 2007 U.S. App. LEXIS 21271, at *3.
2 The patent included an extensive description of mechanical sensors that embodied the invention, but
3 only a conceptual drawing and little description of an electronic sensor that satisfied the claims. *Id.* at
4 *5-6. In particular, the patent included “only one short paragraph and one figure relate[d] to an
5 electronic sensor,” which did “little more than provide an overview of an electronic sensor without
6 providing any details . . . concerning how the electronic sensor is built or operated.” *Id.* at *20.
7

8 The claims were construed to cover both mechanical and electronic sensors, but the court
9 found that the specification “fail[ed] to apprise one of ordinary skill how to make and use the
10 electronic sensor.” *Id.* at *21-22. On that basis, the court found that the claims were invalid as a
11 matter of law. The court held that “in order to fulfill the enablement requirement, the specification
12 must enable the full scope of the claims that includes both electronic and mechanical side impact
13 sensors, which the specification fails to do.” *Id.* at *28; *see also Liebel-Flarsheim Co. v. Medrad,*
14 *Inc.*, 481 F.3d 1371 (Fed. Cir. 2007) (patent invalid because the claims were construed to cover a
15 fluid injector system for a replaceable syringe both with and without a pressure jacket, but the
16 specification only enabled an injector with a pressure jacket).
17

18 The principle underlying the recent *Automotive Techs.* and *Liebel-Flarsheim* decisions is quite
19 old. It dates back at least to the Supreme Court’s decision in *O’Reilly v. Morse*, 56 U.S. 62 (1853).
20 In that case, the Supreme Court considered the validity of claim 8 of Samuel Morse’s patent on the
21 telegraph which purported to cover any use of electromagnetism to print intelligible characters at a
22 distance. *Id.* at 112. The Supreme Court held claim 8 was invalid because it covered more than the
23 one way disclosed in the specification to print characters at a distance using electromagnetism. *Id.* at
24 117 (“for the method or process thus discovered, [Morse] is entitled to a patent. But he has not
25 discovered . . . any other method....”). With respect to the specific invention disclosed in the
26 specification, claim 8 “is outside of it, and the patentee claims beyond it.” *Id.* at 119-20.
27
28

1 Similarly here, Abbott alleges that the asserted claims of the '745 Patent cover co-planar,
 2 amperometric devices. Yet the '745 Patent nowhere discusses how to construct or measure a
 3 measurement zone in a strip having co-planar electrodes which uses amperometry. The '745 Patent
 4 discloses a measurement zone for facing electrode configurations for coulometry and amperometry,
 5 but the claims go beyond that to cover co-planar arrangements for amperometry. The '745 Patent
 6 therefore fails to enable a person of ordinary skill in the art to practice the full scope of the asserted
 7 claims, and is invalid.

9 For similar reasons, the '745 Patent is indefinite because a person of skill in the art could not
 10 determine whether a co-planar, amperometric sensor, such as those accused of infringement in this
 11 case, has a measurement zone as required by the patent claims. 35 U.S.C. § 112, ¶ 2; *Allen Eng'g*
 12 *Corp. v. Bartell Indus.*, 299 F.3d 1336 (Fed. Cir. 2002); *Cardiac Pacemakers, Inc. v. St. Jude Med.,*
 13 *Inc.*, 296 F.3d 1106, 1113 (Fed. Cir. 2002). The '745 Patent explicitly defines the term
 14 "measurement zone" as "a region of the sample chamber sized to contain only that portion of the
 15 sample that is to be interrogated during an analyte assay." (Ex. 1 ('745 Patent) at 7:8-10.) [REDACTED]
 16 [REDACTED]
 17 [REDACTED]
 18 [REDACTED]
 19 [REDACTED]
 20 [REDACTED]
 21 [REDACTED]
 22 [REDACTED]
 23 [REDACTED]
 24 [REDACTED] Accordingly, the term

25 "measurement zone" is indefinite, and the claims invalid.
 26

27 ²⁷ Similarly, he testified that there would be no way to determine if a sensor met the
 28 background signal requirement. (Ex. 2 (Bard Depo.) 147:4-22.)

1 **V. CONCLUSION**

2 For the foregoing reasons, all of the asserted claims of the '745 patent are invalid.

3
4 Dated: October 26, 2007

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